IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Applicant	:	Wallace Lynn Smith
App. No.	:	10/813,080
Filed	:	March 31, 2004
Title	:	METHOD FOR DIAGNOSIS OF PAIN RELIEF PROBABILITY THROUGH MEDICAL TREATMENT
Group/Art Unit:		3736
Examiner	:	Michael C. Astorino
Docket No.	:	86067-001

Delivered via Hand Delivery dated May 19, 2006.

DECLARATION UNDER RULE 132

I, Charles Hamlin, M.D., do hereby declare and say:

1. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereto.

2. My address is 2535 South Downing Street, Suite 500, Denver, Colorado 80210.

3. With regard to my educational background, I have a Bachelor of Arts degree from Yale College, a Bachelor of Medical Science degree from the Dartmouth Medical School, and a Doctor of Medicine degree from Columbia University College of Physicians and Surgeons.

4. With regard to my surgical training, I had my general surgical internship and residency at Roosevelt Hospital in New York and my orthopedic residency at Cornell Medical Center. I

became a Fellow of the American Academy of Orthopedic Surgeons in 1976 and has been an active member of the American Society for Surgery of the hand since 1979.

5. I have been licensed in Colorado to practice medicine since 1972, and became board certified by the American Board of Orthopedic Surgeons in 1974. I entered the private practice for the traumatic and reconstructive surgery of the hand in Denver, Colorado, in 1976, continuing through the present.

6. Among my more than twenty medical publications, authored and co-authored are: Charles Hamlin, Michael Hitchcock, John Hofmeister, and Robert Owens, "Predicting Surgical Outcome for Pain Relief and Return to Work," Best Practices and Benchmarking Healthcare, Mosby - Year Book, Inc. Vol. 1, No. 5 (1996) (hereinafter, "Hamlin et al, 1996 ").

7. I am skilled in the art of medical care as set forth above, and have I have employed Dr. W. Lynn Smith's method for diagnosing the probability of pain relief for patients through medical treatment on several occasions, in the area of orthopedics I have used this method on patients to determine whether medical treatment on hands would be successful given their Pain Index Score. It is my understanding that this method has been well-accepted and relied upon by other medical practitioners, as well, in treatment diagnoses, producing highly beneficial and predictable results.

8. I have assessed Dr. Smith's earlier work in this area with my paper Hamlin et al, 1996. At that time, Dr. Smith's earlier method showed evidence of significant predictability of the probability of pain relief for laminectomy patients (92%) and carpel tunnel patients (90%). *Id* at p. 260. Despite this high level of predictability, evidence of this early work showed a predictability gap between sensitivity scores (a percentage ability to predict somatizers) and specificity scores (a percentage ability to predict non-somatizers). See, Hamlin et al, 1996, Table 2 at p.260. Dr. Smith endeavored to invent a method, his current invention, to reduce this gap.

9. Briefly, the method of the current invention is administered to a patient by having the patient provide written answers or responses to a test, a set of declarative statements, recorded on a response sheet. Once the test containing the declarative statements is completed, nine scoring templates are applied to the answers on the response sheet, for tabulation and evaluation by the method of the patient's responses. Raw scores for certain the validity and clinical factors are recorded on the response sheet, as evaluated by the scoring templates. All of the raw scores, the adjustment scores, and the resultant final scores are all recorded, written down on the response sheet. The method determines the relative importance of all of the scores so that a single Pain Index Score may be determined, and recorded on the response sheet for the particular patient.

10. Dr. Smith developed his current method after determining that certain somatizers can have a poor sense of self, due to a weak ego. Recognition and quantification of this additional factor (the ego integrative defect or E factor) closed the gap between the sensitivity and specificity scores, improving the predictive accuracy to middle to high ninety (95+ % percentages), as I have observed from clinical use of Dr. Smith's method.

11. I have assessed the predictability level of Dr. Smith's present invention for certain of my patients in my own practice of orthopedics. The predictive accuracy of the present invention, Paidex ® Test improved the ability of correctly predicting the probability of pain relief and return to work. The addition of the ego integrative defect factor reduced the gap between sensitivity and specificity, and the predictability of relieving pain and enabling a patient to return to work.

12. In my opinion and clinical observations as set forth below, this Pain Index Score is unique to a particular patient. As I related, and confirmed, in a study of the earlier method by Dr. Smith, and as is even more applicable in the present method invented by Dr. Smith, each patient's responses to the MMPI test questions as administered by this method, can be particularly configured and uniquely assessed by a response analysis into certain validity factor scales and certain clinical factor scales, because no patients' attitudes are naturally configured or arranged in the manner provided by the method of Dr. Smith, either in the earlier method or in the method of the present invention, in the natural world. *See,* Hamlin, et al, 1996.

13. Recent evidence from my analysis confirm the high level of the present method of Dr. Smith. My own clinical observations for patients of mine who have taken this test result in a correct prediction of probability of pain relief and ability to return to work. The results of new patient observations indicate that this method of Dr. Smith is substantially repeatable and highly successful in an ability to predict the probability of pain relief.

14. Therefore, the method of the present invention is highly predictable and produces reliable results upon which a medical doctor can rely. Although two people who have the same actual probability of pain relief may answer the 190 declarative statements in the method somewhat differently, the Pain Index Score will vary only a small percentage given the method of Dr. Smith's invention. In my clinical observations, as well as the analysis of the predictability as set forth above, two patients with the same actual probability of pain relief through medical treatment can be predicted to produce the same analysis and outcome.

15. It is my professional opinion that the method supplies substantially repeatable results for determining the likelihood of success of medical treatment given a patient's pain perception. It is an important self-reporting diagnostic test that identifies and quantifies certain psychological and behavioral, or clinical, factors that can affect medical treatment outcome for a patient sensitive to somatization and thereby can have a critical bearing on a decision by a physician to operate or otherwise medically treat a patient, on predicting problems that could occur post - operatively or after treatment.

16. It is my professional opinion, as well, that this method is a very important practical application in the medical field, and more than a mere manipulation of an abstract idea. I believe this method to be of critical importance and highly useful to the medical community because a patient's perception to pain and pain relief is a significant factor in whether that patient's surgery will be successful. This method transforms patient responses into a concrete number that assists the doctor in determining whether medical treatment will be successful. The work acceptance and interest which I have observed by the medical community, especially by the orthopedic practitioners, confirms its practical and useful application in this field.

SIGNED: Charles Hamlin MD

Charles Hamlin, M.D.

Mary Bengford signed in County of Denver, Colorado.

TESTIFIED DATE: 5/16/06

My Commission Expires
01/04/2010